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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.       |
|---|-------------|----------------------|---------------------------------|------------------------|
| 10/563,451  | 06/05/2006  | Francois Ichas       | REGIM 3.3-073                   | 8046                   |
| 530 7590 03/09/2009<br>LERNER, DAVID, LITTENBERG,<br>KRUMHOLZ & MENTLIK<br>600 SOUTH AVENUE WEST<br>WESTFIELD, NJ 07090 |             |                      | EXAMINER<br>FRONDA, CHRISTIAN L |                        |
|   |             |                      | ART UNIT<br>1652                | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>03/09/2009         | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/563,451

**Applicant(s)**

ICHAS ET AL.

**Examiner**

CHRISTIAN L. FRONDA

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Invention 1     Claims 1-7 and 26, drawn to a method for the demonstration of the occurrence of the molecular event in a cell that leads solubilization and binding of the marker protein.
- Invention 2     Claims 1 and 8, drawn to a method for the demonstration of the occurrence of the molecular event in a cell that leads to cleavage or the modification of the marker protein and solubilizes it.
- Invention 3     Claims 1, 9, and 27, drawn to a method for the demonstration of the occurrence of the molecular event in a cell that leads to the appearance of the subcellular anchoring fragment of the marker protein.
- Invention 4     Claims 1, 10, and 14, drawn to a method for the demonstration of the occurrence of Bax activation.
- Invention 5     Claims 1, 11, 12, and 14, drawn to a method for detecting the activation of a protease.
- Invention 6     Claims 1, 13, and 28, drawn to a method for the demonstration of the occurrence of the molecular event in a cell that is coupled with the measurement of the cell cycle.

- Invention 7    Claims 15-18, drawn to a marker protein.
- Invention 8    Claims 19-22 and 29, drawn to a vector and transformed cell.
- Invention 9    Claim 23, drawn to a non-human transgenic animal.
- Invention 10   Claim 24, drawn to a kit comprising transformed cells or vector.
- Invention 11   Claim 24, drawn to a kit comprising a transgenic animal.
- Invention 12   Claim 25, drawn to a method for evaluating the activity of a candidate anti-cancer compound.

The inventions listed as Inventions 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among Inventions 1-12 is a marker protein for use in the method recited in claim 1 for the demonstration of the occurrence of a specific molecular event in a cell. However, the reference of Wolter et al. (J. Cell Biology, Vol. 139, No. 5, Dec. 1, 1997, pp. 1281-92; reference CK in the IDS filed 07/17/2006) teaches such marker protein and the method recited in claim 1.

Wolter et al. teach a method for the demonstration of an apoptotic event in a cell comprising the binding of solubilized marker protein, such as GFP fused to Bax, Bcl-2, and Bcl-X<sub>L</sub>, which is a direct marker for the occurrence of an apoptotic event, where the marker protein is present in the cell before the detection; and the presence of the marker protein being detected in the cell by any appropriate means including fluorescence microscopy, which makes it possible to determine whether binding and thus apoptotic event has occurred (see entire publication and abstract, especially pages 1281-1286). Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art.

Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Inventions 1-12 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: SEQ ID NOs: 1-14.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the sequences of SEQ ID NOs: 1-14 do not share common structural features, and amino acid and nucleotide compositions.

Applicant is required, in reply to this action, to elect a single species if any one of Inventions 7-12 is elected to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of invention and/or species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention and/or species.

The election of an invention and/or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/  
Patent Examiner  
Art Unit 1652